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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/516,389	06/09/2005	Stanley Frinak	0256.00004	4725

7590 09/07/2007

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EXAMINER	
SAIDI, AZADEH	
ART UNIT	**PAPER NUMBER**
3735	

MAIL DATE	DELIVERY MODE
09/07/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Interview Summary	Application No.	Applicant(s)	
	10/516,389	FRINAK ET AL.	
	Examiner	Art Unit	
	Anita Saidi	3735	

All participants (applicant, applicant's representative, PTO personnel):

(1) *Anita Saidi*. (3) *Kenneth Kohn*.

(2) *Charles Marmor, II*. (4)_____.

Date of Interview: *8/30/07*.

Type: a)☒ Telephonic b)☐ Video Conference
c)☐ Personal [copy given to: 1)☐ applicant 2)☐ applicant's representative]

Exhibit shown or demonstration conducted: d)☐ Yes e)☐ No.
If Yes, brief description: _____.

Claim(s) discussed: *1*.

Identification of prior art discussed: *Levin et al, US patent 4,710,164*.

Agreement with respect to the claims f)☐ was reached. g)☒ was not reached. h)☐ N/A.

Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: *See Continuation Sheet*.

(A fuller description, if necessary, and a copy of the amendments which the examiner agreed would render the claims allowable, if available, must be attached. Also, where no copy of the amendments that would render the claims allowable is available, a summary thereof must be attached.)

THE FORMAL WRITTEN REPLY TO THE LAST OFFICE ACTION MUST INCLUDE THE SUBSTANCE OF THE INTERVIEW. (See MPEP Section 713.04). If a reply to the last Office action has already been filed, APPLICANT IS GIVEN A NON-EXTENDABLE PERIOD OF THE LONGER OF ONE MONTH OR THIRTY DAYS FROM THIS INTERVIEW DATE, OR THE MAILING DATE OF THIS INTERVIEW SUMMARY FORM, WHICHEVER IS LATER, TO FILE A STATEMENT OF THE SUBSTANCE OF THE INTERVIEW. See Summary of Record of Interview requirements on reverse side or on attached sheet.

CHARLES A. MARMOR II
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700
Examiner's signature, if required

Examiner Note: You must sign this form unless it is an Attachment to a signed Office action.

Continuation of Substance of Interview including description of the general nature of what was agreed to if an agreement was reached, or any other comments: Applicant explained alleged differences between the Levin patent and the instant invention. Those differences relates to Levin using a cuff for measuring blood pressure whereas applicant's invention uses an extracorporeal catheter to provide intravascular pressure. A proposed ammendment was discussed. The applicant will add new limitations to further define the claims over the prior art, provided that these new limitations have suppport in the specifications .

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CONFIRMATION:

____ via mail ____ via courier ____ via e-mail ____ will not follow

August 28, 2007

To: Examiner Azadeh Saidi -571.270.3001

Fax No: (571) 271-4001

From: Dr. Kenneth I. Kohn

Re: USSN 10/516,389; Applicant: Frinak, et al.
Attorney Docket: 0256.00004

Total Pages, including this cover sheet: 16

Message:

Examiner, attached herewith please find our Proposed Amendment for our upcoming telephone interview scheduled for Thursday, August 30, 2007, at 11:30 a.m.

If you have any questions regarding the above, please do not hesitate to contact us.

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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of: Frinak, et al.

Serial No. 10/516,389 Group Art Unit: 3709
Confirmation No.: 4725
Filed: 06/09/05 Examiner: SAIDI, Azadeh

For: ACCESS PRESSURE RATIO DEVICE AND TESTING METHOD

Attorney Docket No: 0256.00004

PROPOSED AMENDMENT

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

This is in response to the Office Action dated June 25, 2007, Part of Paper No./Mail Date 20070613. Please amend the application as indicated below, consistent with the instructions found attached hereto:

CLAIMS:

1. (Currently amended) A detection device for detecting ~~irregular~~ intravascular pressure in proximity of a suspected location of irregular blood flow, said device comprising: analyzing means for automatically analyzing extracorporeal blood pressure to derive intravascular pressure ~~upstream of a suspected location of irregular blood flow~~ and comparing the intravascular blood pressure to a standard, ~~whereby~~ and detecting means for detecting and comparing variations in the intravascular blood pressure during multiple tests ~~is indicative of~~ to indicate irregular blood flow.

2. (Currently amended) The device according to claim 1, wherein said analyzing means ~~is computer driven~~ includes a microprocessor.

3. (Currently amended) The device according to claim 2 ~~1~~, wherein said ~~analyzing means is an equation~~ microprocessor includes computing means for computing an algorithm, said algorithm including estimating means for estimating intravascular pressure inside a blood access site to detect potential stenotic lesions in the blood access site due to elevations in intravascular pressure.

4. (Canceled).

5. (Currently amended) The device according to claim 3 4, wherein said algorithm calculates the ratio between intravascular venous blood pressure and mean arterial pressure of the patient.

6. (Currently amended) The device according to claim 1, wherein said detecting means is further defined as detecting and comparing variations in the intravascular blood pressure during multiple tests to detect irregular blood flow ~~for use in~~, said irregular blood flow indicating a risk selected from the group consisting of potential access failure, stroke, heart attack, and stenosis.

7-9. (Canceled).

10. (Currently amended) A method of detecting potentially compromised or irregular blood flow by:

calculating intravascular blood pressure in proximity ~~upstream~~ of a suspected location of irregular blood flow from a measurement of extracorporeal blood pressure; ~~and~~

comparing the calculated intravascular blood pressure to a standard; and

detecting restricted blood flow when ~~whereby~~ elevation of the calculated intravascular blood pressure over a series of calculations is indicated. ~~indicates a restricted blood flow.~~

11 (Currently amended) The method of claim 10, wherein said calculating step further includes automatically calculating intravascular blood pressure.

12. (Currently amended) The method of claim 10, wherein said comparing step further includes automatically comparing the calculated intravascular blood pressure to a standard.

13. (Currently amended) The method of claim 12, wherein said automatically comparing step further includes automatically comparing the calculated intravascular blood pressure to a standard using an algorithm.

14. (Currently amended) The method of claim 10, wherein said calculating step further includes automatically calculating intravascular blood pressure during a procedure.

15. (Currently amended) A system for providing warning of potential health problems due to irregular intravascular pressure, said system comprising: a detection device according to claim 1; and communication means operably connected to said device for communicating a warning when said device indicates an irregularity of intravascular blood pressure when compared to a standard with of at least two uses of said device.

16. (Original) The system according to claim 15, wherein said communication means is selected from the group consisting essentially of electronic communications, facsimile, telephone, cable modem, and T1 connection.

17. (Currently amended) An algorithm on an integrated circuit for detecting irregular intravascular pressure in proximity to an access site for an extracorporeal circuit, including the steps of:

calculating intravascular blood pressure in proximity of a suspected location of reduced blood flow from a measurement of extracorporeal blood pressure;

comparing the calculated intravascular blood pressure to a standard;

repeating the calculating and comparing steps for multiple tests;

determining that an elevation of the calculated intravascular blood pressure over the multiple tests is indicative of restricted blood flow near the access site.

18-21. (Canceled).

22. (Currently amended) An alarm system for use with the algorithm of ~~set for~~ in claim 17 for use in any fluid transporting device or fluid transporting system, said alarm system comprising an integrated circuit for performing the algorithm of claim 17 ~~alarm~~, wherein said algorithm further includes the steps of determining ~~determines~~ an alarm level based on the rate of fluid flow through a device that is part of the alarm system and physical properties of fluid transported through the device; and setting off an alarm based on said determined alarm level. ~~and an alarm is set off based on said algorithm~~.

23. (Original) The alarm system according to claim 22, wherein said alarm level can be set at any value that insures safe operation of the device.

24-25. (Canceled).

REMARKS

Claims 1-25 are currently pending in the application. Claims 1, 10, and 17 are in independent form. Applicants herein cancel claims 4, 7-9, 18-21, and 24-25 without prejudice to further clarify the invention. Figures 2, 3, 6, 7B, and 8 contained clerical errors or were not clear and replacement sheets are enclosed herein. No new matter has been added.

The claims have been amended to more particularly point out and distinctly claim the invention. Support for the amendments can be found throughout the specification as follows:

"Extracorporeal" added to the claims is defined (as its common dictionary definition) as located or occurring outside of the body, and in the present invention, outside of a blood vessel, i.e. tubing that is outside of the patient's body. Support for the word "extracorporeal" in the claims can be found in previously presented claims 19 and 20 (and therefore has already been searched); on pages 12, lines 15-22 ("The algorithm for the present invention can be utilized as an alarm system in any device that transports blood from a patient to an extracorporeal circuit and returns blood to the patient. ... The present device can be utilized as an alarm in plasmapheresis, heart lung machines and any extracorporeal blood treatment or infusion technology circuits."); as well as throughout the examples (VDP calculations are extracorporeal).

"Intravascular" added to the claims has support in many places throughout the specification, for example in the first paragraph of the Detailed Description: "Generally, the present invention provides a detection device and method for detecting variations in intravascular pressure that indicate irregular blood flow. The device includes an analyzer for automatically analyzing intravascular pressure upstream of the

suspected location of irregular blood flow and comparing the intravascular pressure to a standard, whereby variations in the intravascular pressure during multiple tests is indicative of a blood flow restriction."

Support for "detecting means for detecting and comparing variations in the intravascular blood pressure during multiple tests to indicate irregular blood flow" in claim 1 can be found on page 9, lines 2-3 ("...any device that is able to detect variations in ... pressure that indicate irregular blood flow") and page 10, lines 13-15 ("...a device for comparing intravascular pressure to a standard, whereby variation in ... pressure during multiple tests is indicative of irregular blood flow.")

Support for "analyzing means includes a microprocessor" of claim 2 can be found on page 11, lines 2-5 ("...the device includes a replacement of the pressure gauge with a hand-held microprocessor controlled device that measures and records the pressure measurements.")

Support for "computing means for computing an algorithm, said algorithm including estimating means for estimating intravascular pressure inside a blood access site to detect potential stenotic lesions in the blood access site due to elevations in intravascular pressure" of claim 3 can be found various places throughout the specification, for example, in canceled claim 4; page 12, lines 28-31 ("A significant increase in the negative pressure created by the dialysis machine blood pump removing blood from the patient can be used to indicate the presence of an arterial stenosis or an obstruction of the arterial line."); and page 22, lines 28-32 ("The location of an access stenosis, in part, determines the ability of a monitoring system to detect the lesion. In most grafts, a stenotic lesion develops in the region of the venous anastomosis (10, 11, 12, 13). A stenosis in this region or in the central

vein impedes blood flow through the access and increase VAP, which is observed as an increase in VDP.")

Support for "mean arterial pressure of the patient" in claim 5 is found in the fact that artery pressure is determined from a patient's arteries by means of a standard pressure cuff. Support for claim 6 can be found in canceled claims 6-9. Support for claims 10-15 including "extracorporeal" is as stated above. Support for claim 17 can be found in the calculations on pages 14-17 (VAPRT algorithm), Figures 7A-D, and previously presented claim 10. Support for "integrated circuit" in claim 22 can be found on page 10, lines 4-7 ("The algorithm can be used as part of an integrated circuit. This circuit enables the algorithm to be more easily incorporated into a dialysis machine.")

Claims 1-9, 15-16, and 17-23 stand rejected under 35 U.S.C. §112, first paragraph as failing to comply with the enablement requirement. Specifically, the Office Action holds that the analyzing means in the specification has been defined as either a dialysis machine or an equation, but no structure has been associated to it. As for claims 17-23, no structure has been associated with the algorithm, and the nature and body of the algorithm have not been claimed. Applicants point out that the analyzing means is not a hemodialysis machine itself, but rather a separate, computer-driven device attached to the hemodialysis machine ("...the analyzer can include a device that is associated with a hemodialysis machine..." page 9, lines 9-10; "...the device is affixed to a hemodialysis machine..." page 10, lines 15-16). Further, the device need not be attached to the dialysis machine, but can remotely connect to the dialysis machine and all calculations of pressure can be performed at a later time than the dialysis session. Sufficient structure has been provided. Applicants have amended claim 17 to distinctly claim the steps of the algorithm. Claims 18-21 have been canceled, and structure has been added to claim 22 for the alarm system to

include the algorithm - specifically, an integrated circuit has now been included. Reconsideration of the rejection is respectfully requested.

Claims 1-9, 15-16, and 17-23 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention. The Office Action holds that claims 2-3 recite the limitation "analyzing means" and there is insufficient antecedent basis for the limitation. In response thereto, Applicants point out that this is correct use of reference to a means plus function term and there is sufficient antecedent basis. Applicants direct the Office Action to any one of a number of patents containing such language, for example as in U.S. Patent No. 6,343,266 (see claim 1: An anaphora analyzing apparatus comprising: ***analyzing means*** for analyzing an input natural language sentence and outputting analyzed results; storing means for storing the analyzed results outputted from ***said analyzing means***;...), emphasis added. Reconsideration of the rejection is respectfully requested.

Claims 1-9, 15-16, and 17-23 stand rejected under 35 U.S.C. §101 because the claimed invention is directed to non-statutory subject matter. Specifically, the Office Action holds that claims 1-9, 15-16, and 17-23 do not provide a transformation or reduction of an article to a different state or thing, nor do the claims produce a useful and tangible result. The Office Action also holds that claim 2 refers to a computer driven analyzing means, and claim 3 refers to an equation. The claims fail to recite that the instructions are computer executable, and further the instructions do not yield useful and tangible results. Since claims 2 and 3 are dependent on claim 1, and since they are further limiting the scope of claim 1, the Office Action holds that claim 1 is also non-statutory under 35 U.S.C. §101 as not having useful and tangible results. Claims 17-23 are related to an algorithm, and the Office Action holds that the same argument is true for these claims as no structure has been assigned to the algorithm and neither

has the nature of it been described and claimed. In response thereto, Applicants have amended the claims to set forth the necessary structure and produce useful and tangible results. The algorithm calculates intravascular blood pressure to determine that blood flow near the access site is restricted, which puts the patient at risk for clotting or other ailments. Given the detection that this invention provides, medical intervention can occur that will attempt to correct the restriction. Furthermore, the algorithm is included on an integrated circuit. Reconsideration of the rejection is respectfully requested.

Claims 1-16 and 24-25 stand rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,710,164 to Levin, et al. Specifically, the Office Action holds that Levin, et al. discloses a detection device for detecting irregular intravascular pressure comprising analyzing means (10) for automatically analyzing blood pressure upstream of a suspected location of irregular blood flow and comparing the blood pressure to a standard, whereby variations in the blood pressure during multiple tests is indicative of irregular blood flow. The Office Action holds that the analyzing means is computer driven (hemodialysis machine) or an equation (a program on the microprocessor 10) and the equation is an algorithm (programmed microprocessor) that estimates pressure inside a blood access site, thereby detecting irregular blood flow. The Office Action further holds that Levin, et al. discloses a system for providing warning of potential health problems due to irregular intravascular pressure comprising a detection device and communication means (cable/electronic communication for connecting the display to the dialysis machine) operable connected to said device for communicating a warning when said device indicates an irregularity of blood pressure of at least two uses of said device. The Office Action holds that the calculating step includes automatically calculating blood pressure during a procedure, the comparing step includes automatically comparing the blood pressure to a standard, and the automatically comparing step further includes automatically comparing the blood

pressure to a standard using an algorithm. Reconsideration of the rejection under 35 U.S.C. § 102(b), as anticipated by Levin, et al., as applied to the claims is respectfully requested. Anticipation has always been held to require absolute identity in structure between the claimed structure and a structure disclosed in a single reference.

In Hybritech Inc. v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 231 U.S.P.Q. 81 (Fed. Cir. 1986) it was stated: "For prior art to anticipate under §102 it has to meet every element of the claimed invention."

In Richardson v. Suzuki Motor Co., Ltd., 868 F.2d 1226, 9 U.S.P.Q.2d 1913 (Fed. Cir. 1989) it was stated: "Every element of the claimed invention must be literally present, arranged as in the claim."

Levin, et al. discloses a method and system for continuously monitoring patient heart rate and mean arterial blood pressure during hemodialysis and for automatically controlling fluid extraction rate and/or dialysate sodium concentration in the event that blood pressure and/or heart rate indicate onset or impending onset of a patient hypotensive episode. There are three separate machines for performing these functions: an automated blood pressure monitor, an automated patient heart rate monitor, and the hemodialysis machine. The blood pressure monitor is essentially a device for measuring blood pressure based on the blood in the patient's arm, i.e. a cuff that inflates and deflates automatically to read the diastolic and systolic blood pressure readings. In other words, the device of Levin, et al. merely takes the place of an actual technician to take a blood pressure reading. The blood pressure readings referred to in this patient are derived from a standard blood pressure cuff on the patient's arm and not from the intravascular blood near the access site for an extracorporeal circuit. There are no extracorporeal blood readings

performed. No blood is at any time removed from the patient to take a measurement and neither is there any suggestion to do so.

In contradistinction, the presently pending amended claims require a measurement and analysis of extracorporeal blood pressure, i.e. blood that is outside of the body made possible by a vascular access port, in order to indicate irregular intravascular blood flow. The analysis of the extracorporeal blood pressure of the present invention provides a unique method of determining potential problems within the patient's intravascular blood stream in proximity of the access. Therefore, since the Levin, et al. patent does not disclose analyzing or measuring extracorporeal blood pressure to derive intravascular blood pressure as set forth in the presently pending independent claims, the claims are patentable over the Levin, et al. patent and reconsideration of the rejection is respectfully requested.

The remaining dependent claims not specifically discussed herein are ultimately dependent upon the independent claims. References as applied against these dependent claims do not make up for the deficiencies of those references as discussed above, and the prior art references do not disclose the characterizing features of the independent claims discussed above. Hence, it is respectfully submitted that all of the pending claims are patentable over the prior art.

In view of the present amendment and foregoing remarks, reconsideration of the rejections and advancement of the case to issue are respectfully requested.

The Commissioner is authorized to charge any fee or credit any overpayment in connection with this communication to our Deposit Account No. 11-1449.

Respectfully submitted,

KOHN & ASSOCIATES, PLLC

Kenneth I. Kohn, Reg. No. 30,955
Customer No.: 48924

Dated: August 27, 2007

CERTIFICATE OF ELECTRONIC FILING VIA EFS-WEB

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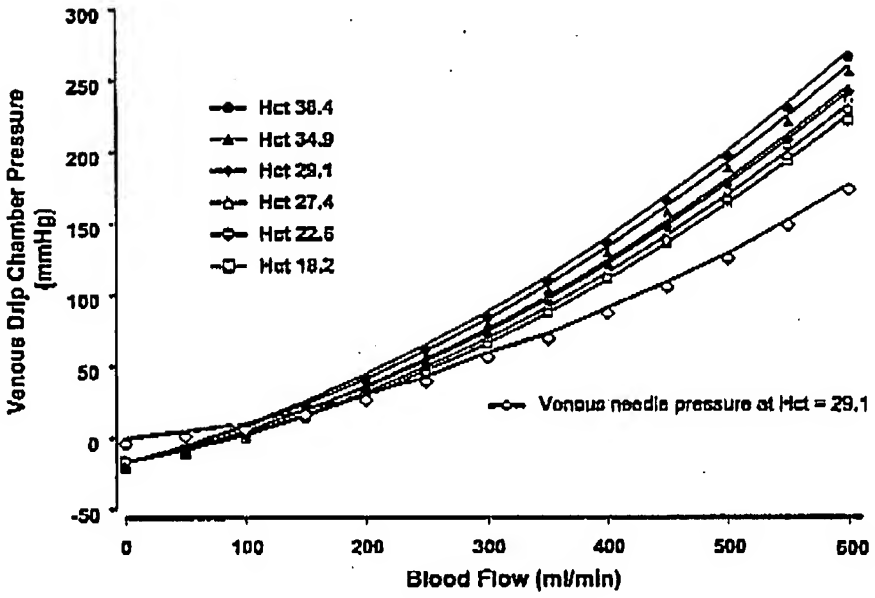

Figure 2

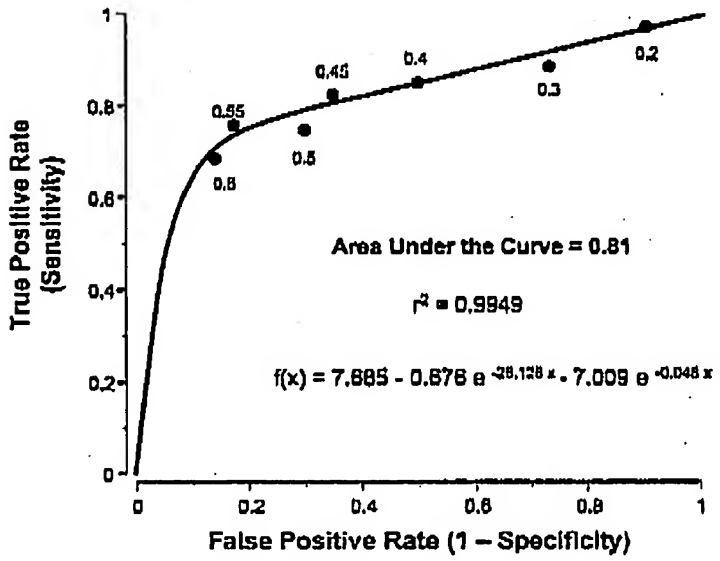

Figure 3

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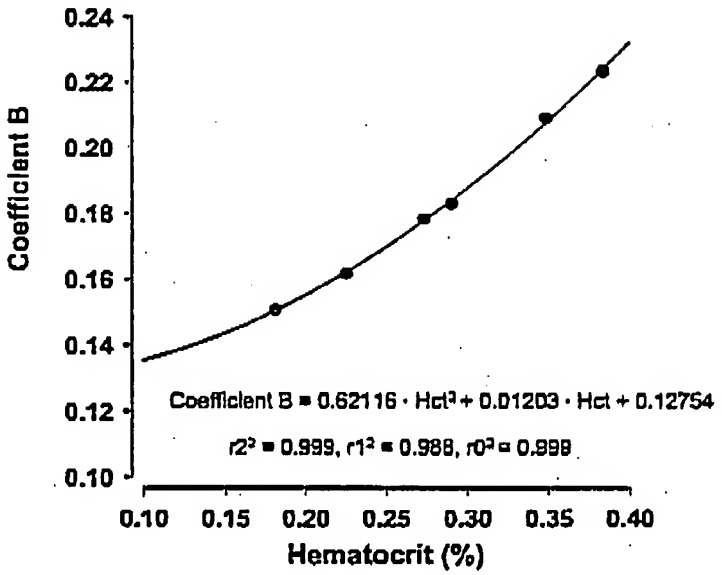

Figure 6

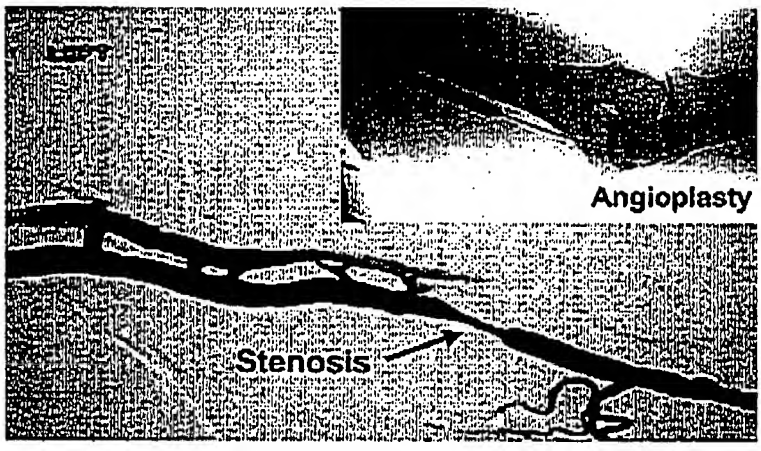

Figure 8

REPLACEMENT SHEET

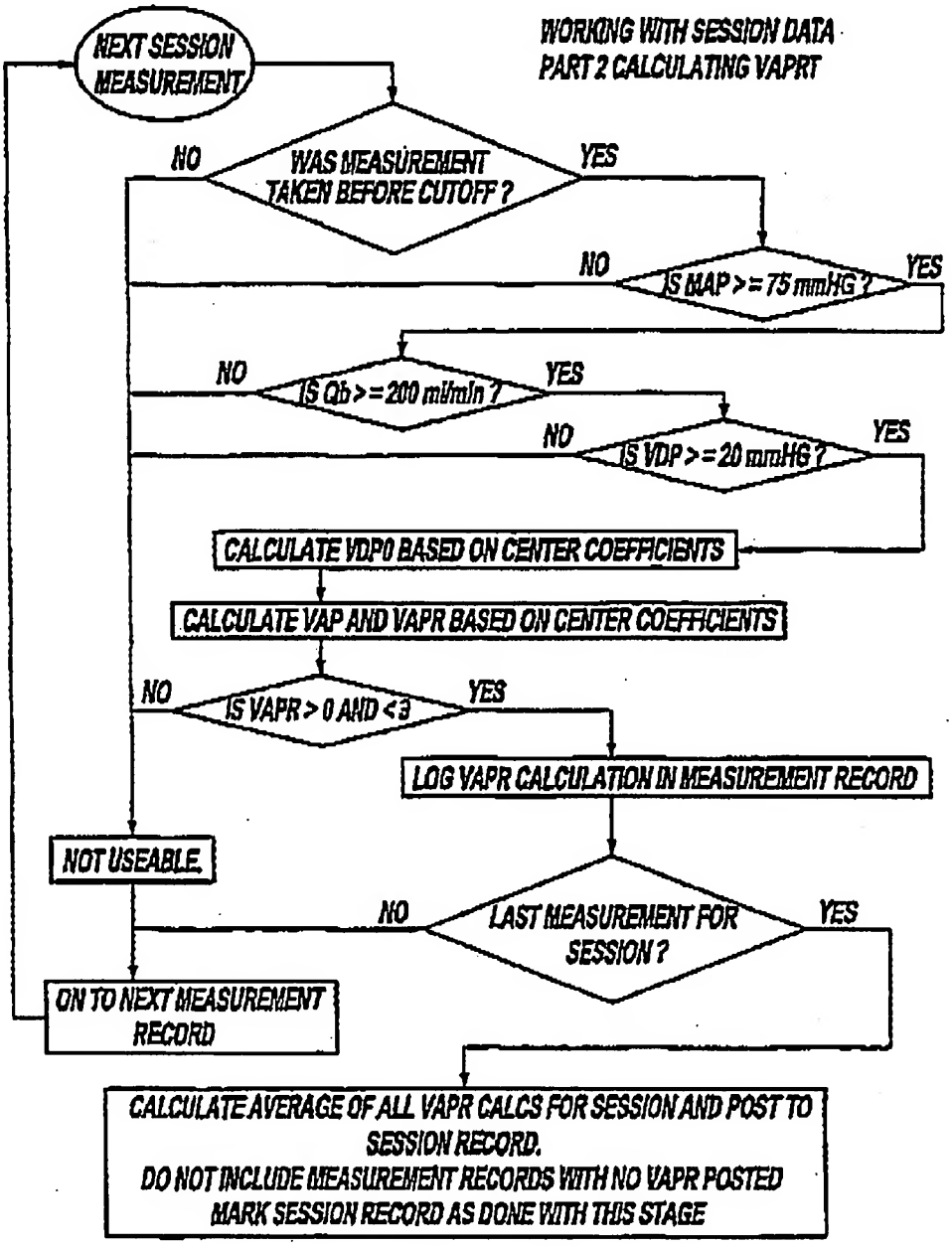

Figure - 7B